

## **OPEN HEART SURGERY SERVICES REVIEW CRITERIA**

**(DRAFT as of 9/11/03)**

### **DEFINITIONS**

Adult means a person 18 years of age and older.

Open Heart Surgery means any invasive surgical procedure performed directly on the heart or the intra-thoracic great vessels, to correct acquired or congenital defects, to replace diseased valves, to open or bypass blocked vessels, or to graft a prosthesis or a transplant in place. In open heart procedures, the heart chambers are open and fully visible, and blood is detoured around the surgical field by a heart-lung bypass machine unless the procedure involved is a minimally invasive coronary artery bypass graft. In the latter case, a heart-lung machine might not be used, but must still be available in the operating room on a stand-by basis.

Open Heart Surgery Service means an organized surgical program which serves the inpatients of a hospital in an operating room or suite of rooms equipped and staffed to perform open heart surgery. Additionally, an open heart surgery service shall have an intensive care unit, cardiac catheterization laboratory and all other support services required to support and care for open heart surgery patients.

Open Heart Surgery Case means a surgical procedure or combination of procedures performed in a single session in the operating room on the heart or intra-thoracic great vessels.

Publicly Available Data means open heart surgery counts based upon the most current publicly available data from the Joint Annual Reports of Hospitals and from the hospital UB-92 database. For data not included in these data systems, preference should be given to verifiable data sources. All data used in the completion of the application should include clear statements of the sources of all data provided.

Service Area means the geographic area defined in terms of counties represented by an applicant as the reasonable area to which a health care institution intends to provide open heart surgery services, and in which at least 75% of its service recipients reside.

## **STANDARDS**

The need for open heart surgery services is determined by following criteria:

1. The need for open heart surgery services in a particular service area is determined by applying the following formula:

$$N = U \times P + O$$

Where: N = Number of cases needed in a service area.

U = Utilization rate (number of procedures performed per 1,000 population in Tennessee on Tennessee residents as determined by the State Department of Health).

P = Population for the service area as determined by State Department of Health actual data or estimates.

O = The number of procedures performed in the service area on out-of-state residents in the same time frame used to determine U (utilization for Tennessee residents).

The need for pediatric and adult open heart surgery services should be projected separately. Use rates and population rates should be based upon the age-specific rates for adult and pediatric populations intended to be served.

2. The need for open heart surgery services shall be projected three years into the future from the current year.
3. Adult open heart surgery programs shall perform at least 200 cases per year within three years of initiation and each year thereafter. Pediatric open heart surgery programs shall perform at least 130 cases per year within three years of initiation and each year thereafter. Pediatric open heart surgery programs should be located in hospitals where hospital based pediatric cardiology programs exist.
4. No new open heart surgery programs shall be approved if the new program will cause the annual caseload of any existing programs providing open heart surgery services within the service area to drop below 350 adult cases or 130 pediatric cases. The need for additional services will be determined by comparing the existing utilization in the service area to the number of needed services. Existing capacity will be determined by multiplying the number of open heart surgery providers in the service area by 350 for adult and 130 for pediatric. For services

that are approved but not built or in review, the projected utilization from the CON application will be used to quantify the existing capacity. The total capacity is then compared with the need for open heart services calculated by the formula in item 1 above.

Each applicant must provide publicly available data to show where all of the residents of the proposed service area, who received open heart procedures during a defined 12-month period prior to the application went to receive services. These data should include all facilities that provided open heart services to the residents of the service area, the number of open heart surgeries performed on residents of the service area for each facility as well as the total number of open heart surgeries performed in each facility. The data should be for the most current 12-month period prior to the application date for which data are publicly available. Based on these data, the applicant for the new service must demonstrate the impact on current providers that are serving residents of the same service area.

5. A facility requesting approval to add a new open heart surgery program must have an existing cardiac catheterization laboratory capable of performing therapeutic procedures, an intensive care unit and all other support services required to care for open heart surgery patients.
6. Staffing - The physician(s) performing the open heart surgical procedures should be board certified/eligible in cardiovascular surgery.